510(k) Summary

APR 2 8 2014

This 510(k) Summary information is supplied in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510 (k) number is K133652

Date: April 28, 2014

Submitted by:

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Trade Name: GSP Neonatal Total Galactose kit (3309-001U)

Common Name: Galactose test system
Regulation: 21 CFR 862.1310

Classification Name: Galactose test system

Classification: I, Reserved

Panel: 75 Clinical Chemistry

Product Code: JIA

Predicate device: Neonatal Total Galactose kit [K071649]; Wallac Oy

Device Description:

The GSP Neonatal Total Galactose kit contains sufficient reagents to perform 1152 assays. The GSP Neonatal Total Galactose test system measures total galactose, i.e. both galactose and galactose-1-phosphate, using a fluorescent galactose oxidase method. The fluorescence is measured using an excitation wavelength of 505 nm and an emission wavelength of 580 nm.

The kit contains the following components:

Calibrators have been prepared from human red blood cells enriched with galactose, and with ProClin 300 as preservative. The hematocrit value is 50 - 55 % to correspond to a hematocrit of a newborn. The calibrators have been calibrated against primary calibrators gravimetrically prepared using a U.S. Pharmacopeia Reference Standard Preparation for galactose.

Controls have been prepared from human blood enriched with galactose and galactose-1-phosphate, and with ProClin 300 as preservative. Prior to dispensing the blood onto the filter paper, the hematocrit value of blood used in the controls preparation is adjusted to 50 - 55 % to correspond to a hematocrit of a newborn. The low control is approximately 4.0 mg/dL and the high control approximately 12 mg/dL.

All human source materials used in the preparation of kit components were tested and found to be non-reactive for the presence of HBsAg, anti-HIV 1 and 2, and HCV by FDA approved methods.

Neonatal Total Galactose Assay Reagent 1 – 3 lyophilized vials
Neonatal Total Galactose Assay Reagent 2 – 3 lyophilized vials
Neonatal Total Galactose Assay Buffer – 3 bottles, 40 ml
Neonatal Total Galactose Assay Reconstitution Solution – 1 bottle, 20 ml
Neonatal Extraction Solution – 1 bottle, 60 ml

Intended Use:

The GSP Neonatal Total Galactose kit is intended for the quantitative determination of total galactose (galactose and galactose-1-phosphate) concentrations in blood specimens dried on filter paper as an aid in screening newborns for galactosemia using the GSP® instrument.

Comparison Chart:

Comparison of the GSP Neonatal Total Galactose device with its predicate:

GSP Neonatal Total Galactose kit		
Characteristics	**Proposed Device**	**Predicate (K071649)**
Intended Use/Indications for Use	The GSP Neonatal Total Galactose kit is intended for the quantitative determination of total galactose (galactose and galactose-1-phosphate) concentrations in blood specimens dried on filter paper as an aid in screening newborns for galactosemia using the GSP® instrument.	This kit is intended for the quantitative determination of total galactose (galactose and galactose-1-phosphate) concentrations in blood specimens dried on filter paper as an aid in screening newborns for galactosemia.
Test Methodology	Enzymatic assay	Same
Detection Method	Fluorescence – measured at 505 nm and 580 nm wavelengths	Fluorescence – measured at 340 nm and 405 nm wavelengths
Instrument Platform	GSP instrument, automated (K090846)	Fluorometer, manual
Sample Type	Dried blood spot	Same
Reportable Range	1.15 – 50 mg/dL	1.3 – 40 mg/dL
Lower Limits of Measure	LoB = 0.34 mg/dL LoD = 0.97 mg/dL LoQ = 1.15 mg/dL	LoB = 0.7 mg/dL LoD = 1.3 mg/dL
Calibrators	A – 0.5 mg/dL B – 2.5 mg/dL C – 5.0 mg/dL D – 10.0 mg/dL E – 20 mg/dL F – 50 mg/dL	A – 0 mg/dL B – 1.5 mg/dL C – 4.0 mg/dL D – 9.0 mg/dL E – 18 mg/dL F – 40 mg/dL

Summary of Non-Clinical Studies:

The variation of the GSP Neonatal Total Galactose assay was determined using dried blood spot samples, 3 kit lots, and 3 GSP instruments. The study was performed in 27 runs over 21 days, each run consisting of 2 plates with 4 replicates per sample. Total number of measurements was 216 per each of seven samples. Total variation ranged from 9.3 to 14.1 %CV.

The Limit of Blank (LoB) for total galactose is 0.34 mg/dL, defined as the 95th percentile of a distribution of blank samples (n = 150). The Limit of Detection (LoD) is 0.97 mg/dL based on 216 determinations of 4 low level samples. The Limit of Quantitation (LoQ) is 1.15 mg/dL, defined as the lowest concentration with a total CV equal to or less than 20%.

For the GSP Neonatal Total Galactose kit, the assay has been demonstrated to be linear throughout the measuring range (from 1.15 mg/dL to 50 mg/dL).

The recovery of galactose, galactose-1-phosphate, and both combined was determined from three contrived dried blood spot samples with an average recovery of 109%, 117% and 103%, respectively.

The potentially interfering substances were added to whole blood with three total galactose concentrations (5, 10, and 15 mg/dL). A bias exceeding ±15% is considered a significant interference. Acetaminophen and conjugated bilirubin were found to interfere with the assay by decreasing the measured total galactose concentration (see the tables below). Acetaminophen concentrations above 2.75 mg/dL and conjugated bilirubin concentrations above 16.6 mg/dL may cause a false negative screening result for a specimen with measured total galactose concentration close to the cut-off value.

Total Galactose conc. (mg/dL)	Acetaminophen Concentration tested mg/dL	Percent change in measured galactose (%)	Significant change
5	1.38	-9.6	No
	2.75	-9.3	No
	4.13	-20.6	Yes
	5.5	-22.4	Yes
10	1.38	-7.1	No
	2.75	-11.8	No
	4.13	-20.4	Yes
	5.5	-21.9	Yes
15	1.38	-7.5	No
	2.75	-11.6	No
	4.13	-20.5	Yes
	5.5	-21.8	Yes

Total Galactose conc. (mg/dL)	Conjugated bilirubin Concentration tested mg/dL	Percent change in measured galactose (%)	Significant change
5	8.3	-6.0	No
	16.6	-10.3	No
	24.9	-100	Yes
	33.2	-100	Yes
10	8.3	-1.6	No
	16.6	-2.7	No
	24.9	-16.3	Yes
	33.2	-99.9	Yes
15	8.3	5.9	No
	16.6	9.3	No
	24.9	4.4	No
	33.2	-25.6	Yes

Intralipid[1] was found to not interfere up to added concentrations of 250 mg/dL at 5 and 10 mg/dL total galactose; and up to 375 mg/dl at 15 mg/dl total galactose. When present above these amounts Intralipid may cause a false positive screening result for a specimen with measured total galactose concentration close to the cut-off value.

Total Galactose conc. (mg/dL)	Intralipid Concentration tested mg/dL	Percent change in measured galactose (%)	Significant change
5	125	6	No
	250	10	No
	375	23	Yes
	500	33	Yes
	750	37	Yes
	1130	54	Yes
	1500	77	Yes
10	125	15	No
	250	13	No
	375	19	Yes
	500	19	Yes
	750	30	Yes
	1130	40	Yes
	1500	52	Yes
15	125	4	No
	250	13	No
	375	15	No
	500	24	Yes
	750	22	Yes
	1130	22	Yes
	1500	29	Yes

In addition, hemoglobin in combination with elevated bilirubin concentration of 15 mg/dL was found to interfere with the assay by increasing the measured total galactose concentration (see the table below). Therefore, hemoglobin level at 198 g/L and above in combination with elevated bilirubin level may cause a false positive screening result for a specimen with measured total galactose concentration close to the cut-off value .

Total Galactose conc. (mg/dL)	Hemoglobin Concentration tested g/L at Bilirubin level 15 mg/dL	Percent change in measured galactose (%)	Significant change
5	102	-0.8	No
	198	26.3	Yes
	217	5.1	No

[1] Intralipid is a registered trademark of Fresenius Kabi AB.

	230	4.0	No
10	102	2.2	No
	198	19.3	Yes
	217	-11.0	No
	230	7.1	No
15*	102	3.5	No
	198	5.8	No
	230	22.0	Yes

*Due to insufficient blood volume during sample preparation, a hemoglobin sample at 217 g/L could not be prepared at 15 mg/dL total galactose.

Hematocrit levels from 30% to 66% (Hemoglobin levels 102–230 g/L) were found not to interfere at total galactose concentrations of 5, 10 and 15 mg/dL.

The following substances were tested and found to not interfere with the measurement of total galactose for the concentration noted; Unconjugated bilirubin (20 mg/dL), β-Nicotinamide adenine dinucleotide (100 µmol/L), Glutathione (3 mmol/L), Human Serum Albumin (30 mg/mL), Ascorbate (6 mg/dL), D-glucose (1000 mg/dL), D-mannose (100 mg/dL), D-fructose (18 mg/dL), Ampicillin (152 µmol/L), and Lithium heparin (0.375 mg/ml).

Summary of Internal Method Comparison and Screening Performance Studies:

The 3309-001U GSP Neonatal Total Galactose kit (y) was compared internally with the 3029-0010 Neonatal Total Galactose kit (x) using routine screening and spiked blood spot specimens, duplicate measurements, in the range of 1.3–40 mg/dL (72–2220 µmol/L) in the 3029-0010 kit, the range in the 3309-001U kit being 1.15–50 mg/dL (64–2775 µmol/L. The correlation from weighted Deming regression was found to be: mg/dL: y= 1.16x - 0.49; 95% CI: slope (1.07; 1.26), intercept (-0.73; -0.25) (n=141).

The GSP Neonatal Total Galactose test system was designed with an adjusted calibration (shift of approximately 20%) to better align performance with CDC Newborn Screening Quality Assurance Program control material. Therefore current Neonatal Total Galactose users will observe an increased recovery with the GSP Neonatal Total Galactose when running the same samples on both test systems.

In a study conducted at one newborn screening laboratory in the United States, the screening performance of the new and predicate device was evaluated with a total of 2320 samples (6 confirmed positive samples and 2314 routine samples). The screening performance is shown below based on 95.0 and 99.0 percentile values.

Screening performance of GSP Neonatal Total Galactose test system (95.0 percentile).

GSP result	Manual result	Total	Positive	Normal
+	+	82	6	76
+	-	45	0	45
-	+	47	0	47
-	-	2146	0	2146
Total		2320	6	2314

Overall percent agreement = (82+ 2146) / 2320* 100% = 96.0 %
Positive percent agreement = (82/129) * 100% = 63.6 %
Negative percent agreement = (2146/ 2191) * 100% = 97.9%

Screening performance of GSP Neonatal Total Galactose test system (99.0 percentile).

GSP result	Manual result	Total	Positive	Normal
+	+	16	6	10
+	-	14	0	14
-	+	14	0	14
-	-	2276	0	2276
Total		2320	6	2314

Overall percent agreement = (16+ 2276) / 2320* 100% = 98.8%
Positive percent agreement = (16/30) * 100% = 53.3 %
Negative percent agreement = (2276/ 2290) * 100% = 99.4%

Substantial Equivalency:

The proposed device and predicate device utilize similar enzymatic pathway and design shown to produce equivalent screening performance in a clinical setting. Both devices are intended for use in for the quantitative determination of total galactose (galactose and galactose-1-phosphate) concentrations in blood specimens dried on filter paper as an aid in screening newborns for galactosemia

Conclusion:

The GSP Neonatal Total Galactose test system demonstrates analytical and screening performance that supports its substantial equivalency with the predicate device, the Neonatal Total Galactose test system (K071649).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 28, 2014

WALLAC OY, A SUBSIDIARY OF PERKIN ELMER, INC.
C/O JEANETTE SCHIER-PUGSLEY
DIRECTOR OF REGULATORY AFFAIRS
940 WINTER STREET
WALTHAM MA 02451

Re: K133652
Trade/Device Name: GSP Neonatal Total Galactose Kit
Regulation Number: 21 CFR 862.1310
Regulation Name: Galactose test system
Regulatory Class: I, Reserved
Product Code: JIA
Dated: April 14, 2014
Received: April 15, 2014

Dear Ms. Jeanette Schier-Pugsley:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Courtney H. Lias -S

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
k133652

Device Name
GSP Neonatal Total Galactose kit

Indications for Use *(Describe)*

The GSP Neonatal Total Galactose kit is intended for the quantitative determination of total galactose (galactose and galactose-1-phosphate) concentrations in blood specimens dried on filter paper as an aid in screening newborns for galactosemia using the GSP® instrument.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Yung W. Chan -S

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